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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/469,492	06/06/1995	HOWARD WEINER	1010/16959-U	6384

7590 01/28/2003

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EXAMINER
DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No. 08/469,492	Applicant(s) Weiner et al
	Examiner Patricia A. Duffy	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 4, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *37, 42-44, 46, 48, 52, 53, 54, 56, and 57* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *37, 42-44, 46, 48, 52, 53, 54, 56, and 57* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-4-02 has been entered.

2. The amendment filed 11-4-02 has been entered into the record. Claims 37, 42-44, 46, 48, 52-54, 56 and 57 are pending and under examination.

3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

4. The provisional obvious double patenting rejections are withdrawn in view of the properly filed terminal disclaimer.

Rejections Maintained

5. The rejection of claims 37, 42-44, 46, 52, 53, 54, 56 and 57 under 35 U.S.C. 112, first paragraph is maintained for all reasons made of record for claims 37-58 in Paper No. 6, mailed 12-31-96 and maintained in each subsequent office action thereafter.

Applicants response has been carefully considered but is not persuasive. Applicants indicate that the independent claims 37, 46 and 48 have been amended to make it even more clear that the claims do not encompass "prevention" of disease. This is not persuasive, "treat" has been specifically defined as encompassing prevention of disease in the specification as originally filed. One clearly can substitute "prevent" for treat in the

claims to read -A method for preventing an autoimmune disease in a human or rodent host by suppressing an ongoing autoimmune response associated with said disease...- As such, the claims still clearly encompass prevention. Applicants are directed to the examiners suggestion below to obviate this issue. Applicants argue that what is an autoantigen for one individual is not necessarily an autoantigen for another individual and this aspect of the rejection is withdrawn in view of Hafler et al and a review of the art. The examiner appreciates the clarification of the previous arguments with respect to OVA. However, it is still noted that the Applicants acknowledge that the response that must be generated by the fed antigen is "oral tolerization" and that it is the oral tolerization to the bystander antigen that generates that non-specific immunosuppressive cytokines that suppress in a bystander manner the autoimmune response. The immune response to the bystander antigen must be specific and must be tolerizing. Bystander suppression of the autoimmune T cells in fact relies upon an antigen specific response to the bystander. The response to the bystander antigen must be specific and must be tolerizing. Bystander suppression in fact relies upon an antigen specific response. As such, everything the examiner has presented with respect to the unpredictability of "oral tolerization" to any antigen is highly relevant in this case. The general applicability of the art of tolerization is highly relevant here because if one skilled in the art could not predictably tolerize to fed or inhaled antigens, one can not predictably suppress cells to a different antigen (i.e. the bystander effect) by means of elicitation of a OVA-specific tolerization response. While the suppression of the heterologous immune response may be non-specific, the generation of the mediators is highly bystander antigen tolerization dependent. Tisch et al is in fact highly relevant to the enablement of these broad claims. Tisch et al (Proc. Natl. Acad. Sci. USA 91: 437-438, 1994) specifically talks about antigen-driven bystander suppression

and teach that the induction of antigen-specific CD8+ regulatory T cells is "... an effect that is often variable and highly dose dependent" (page 438, column 1, last paragraph). Tisch et al describes that "While oral administration of antigen appears to be non-toxic, its effects are variable and highly dose specific " and that "It is naive to expect that one form of antigen-specific immunotherapy will be effective in the treatment of all T-cell mediated autoimmune diseases." As such, the suppressive or tolerizing response is generated to the administered "bystander antigen", and the cytokines produced by the suppressive response induced by the bystander antigen, provide for suppression of the targeted autoimmune response in a "bystander" non-specific manner. This does not obviate the fact that the ability of the bystander antigen to induce a specific suppressive immune response is critical to the enablement of the claims. Tisch et al teaches that the ability of any antigen to induce a suppressive response is unpredictable and the subsequent downstream response of the ability to produce a bystander effect by suppressing other antigen-responses in a non-specific manner is relevant and on point to this enablement rejection.

The rejection is maintained.

Status of Claims

6. All claims stand rejected.

Allowable Subject Matter

Claim A. A method for suppressing an autoimmune response associated with Type I diabetes in a human or rodent host having said Type I diabetes, the method comprising

administering by mouth to said host an amount of a composition comprising glucagon in an amount effective for suppressing said response.

Conclusion

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should

applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
January 27, 2003

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600